



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

08/939,905

09/29/1997

MARK GIJZEN

76.105

4378

23117

7590

03/31/2005

NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER

MARSCHER, ARDIN H

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/939,905	Applicant(s) GIJZEN, MARK	
	Examiner Ardin Marschel	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-33, & 36-39 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3, 4, 15, 17, 19, 21, 23, 25 and 27 is/are allowed.
- 6) ☒ Claim(s) 2, 7, 9-14, 16, 18, 20, 22, 24, 26, 28-33, & 36-39 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>(1 sheet)</u> . | 6) <input type="checkbox"/> Other: _____ |

Handwritten mark

DETAILED ACTION

Applicants' arguments, filed 12/23/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Unfortunately, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application. The response time is restarted as of the mailing of this office action.

The amendment, filed 12/23/04, has been entered. Due to the newly applied rejections summarized below, the finality of the previous office action, mailed 10/20/04, is hereby withdrawn.

LACK OF WRITTEN DESCRIPTION BASED ON NEW MATTER

Claims 32 and 36-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Reconsideration of the instant application, as filed, has failed to reveal written description for isolated DNA molecules as short as 20 contiguous nucleotides in length which have transcriptional regulatory activity as previously amended via the addition of claims 32 and those dependent therefrom. Therefore, claim 32 contains NEW MATTER as well as claims which depend from claim 32 directly or indirectly.

LACK OF SCOPE OF ENABLEMENT

Claims 2, 7, 9-14, 16, 18, 20, 22, 24, 26, 28-33, and 36-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA molecule which has transcriptional regulatory activity which is the DNA molecule comprising nucleotides 1-1532 of SEQ ID NO: 2, does not reasonably provide enablement for other transcriptional regulatory activity possessing DNA molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

In the amendment, filed 6/17/04, applicant added limitations to numerous claims

directed to require "transcriptional regulatory activity" for claimed DNA molecule subject matter. Instant claim 2 is representative of subject matter with this limitation and additionally with being inclusive of segments of "at least 24 contiguous nucleotides selected from nucleotides 1-1532 of SEQ ID NO: 2". On page 5, lines 8-10, of the instant specification a regulatory region is cited as having nucleotides 1-1532 of SEQ ID NO: 2 which is interpreted as disclosing this entire 1532 sequence as regulatory. Then in the specification on page 5, lines 10-21, various DNA segments are described but without indicating that these are regulatory in any way. On page 6, line 7, through page 7, line 8, DNA regulatory elements are cited inclusive of various segments of SEQ ID NO: 2. DNA regulatory regions, promoters, etc. are generically defined on page 13, line 9, through page 14, line 17. In the instant specification on page 19, lines 14-20, the genomic sequence of SEQ ID NO: 2 is characterized by a series of exons and introns spanning nucleotides 1533 to 4516. Two upstream regulatory regions are described via a TATA box and cap signal (without an indication of specific start and end nucleotides for these regions) within the 1-1532 segment of SEQ ID NO: 2, but no others.

Polyadenylation signals at the other end of SEQ ID NO: 2 in the region of nucleotides 4520 – 4700 are also disclosed but are not described as being regulatory. SEQ ID NO: 2 as characterized by the page 19 summary fits the expected commonly understood structure of a gene with both upstream regulatory regions followed by a section of exons and introns for the structural amino acid coding region thereof. Such a gene structure is shown in the well known textbook by Lehninger at pages 731-734 and depicted in Figures 32-1 and 32-2 therein. The Lehninger description supports the concept that

Art Unit: 1631

specific segments in an upstream regulatory region function specifically as an operator, regulator gene, etc. This clearly casts significant doubt on the predictability that any 24 contiguous segment as embodiments within instant claim 2 has transcriptional regulatory activity. Instant claim 2 is not limited to either the TATA box or cap signal segments as cited in the specification on page 19. This same lack of predictable enablement also exists for claim 7, and similarly for claim 32, and claims 16, 18, 20, 22, 24, 26, and 28-31, 33, and 36-39, which depend directly or indirectly from either of claims 2, 7, or 32.

Another issue of lack of enablement exists for claims 9-14. These claims cite nucleotide regions from within the structural portions of SEQ ID NO: 2 and also confusingly requires that they have transcriptional regulatory activity. Given the disclosure of exons and introns in the region 1533 – 4700 of SEQ ID NO: 2, it is unpredictable that transcriptional regulatory segments are contained therein and thus lacking in enablement, both regarding instant disclosures as well as well known gene segmentation as in Lehninger as described above.

POTENTIAL INTERFERENCE

An interference proceeding may be initiated wherein instant claims 2, 7, 16, 18, 20, 22, 24, 26, and 28-31 would correspond to interfering subject matter with claims 1-27 of Vierling, Jr. (U.S. Patent 6,586,583). Vierling, Jr. would be designated junior party in such a proceeding. An interference would only be pursued after at least one claim corresponding to the interfering subject matter is deemed allowable.

CLAIM OBJECTION

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1, 3, 4, 15, 17, 19, 21, 23, 25, and 27 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 26, 2005

Ardin H. Marschel 3/26/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER